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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
(Docket No. 400188)

In re the Application of: )  
 )  
DOMINGUEZ ET AL. )  
 ) Art Unit: 3763  
Serial No.: 10/681,602 )  
 )  
Filed: October 8, 2003 ) Examiner  
 )  
For: DELIVERY SYSTEM USING BALLOON )  
SYSTEM )

**DECLARATION OF GEORGE H. GERSTMAN UNDER 37 C.F.R. §1.131**

George H. Gerstman declares as follows:

1. I am partner in the law firm of Seyfarth Shaw LLP, 55 East Monroe Street, Suite 4200, Chicago, Illinois 60603.
2. I am a former patent examiner and a registered patent attorney (Reg. No. 22,419).
3. I am very familiar with the above identified application. I aided in the preparation of the parent application, Serial No. 09/878,530 filed June 11, 2001.
4. To show that there was reasonable diligence with respect to the invention of claims 1-10 from prior to December 7, 2000 until the June 11, 2001 filing date of the parent application, I have attached certain documents and I state the following:
5. The invention was referred to as IR 00/187. A patentability search with respect to the invention was completed on October 18, 2000. A redacted portion of the searcher's October 18, 2000 patentability report is attached as Exhibit 1.
6. On March 27, 2001, I was sent, via Federal Express, the invention disclosure IR 00/187. A copy of IR 00/187 (with dates redacted) is attached as Exhibit

2. A copy of the e-mail message, partially redacted, indicating that the invention record is being forwarded to me, is attached as Exhibit 3. As pointed out in the e-mail message of Exhibit 3, the invention was given top priority.

7. On March 28, 2001, I prepared a memorandum concerning the present invention. As indicated in the invention record, the e-mail and my March 28, 2001 memorandum, the invention was referred to as IR 00/187. A redacted copy of my March 28, 2001 memorandum is attached as Exhibit 4.

8. On April 4, 2001, I completed a draft of the patent application and forwarded it to Henry W. Collins, a patent attorney with Johnson & Johnson (Cordis is a wholly-owned Johnson & Johnson company), the assignee. A copy of my April 4, 2001 letter to Mr. Collins is attached as Exhibit 5.

9. On April 20, 2001, the draft of the patent application was forwarded to inventor Larry Dominguez for review. A copy of the April 20, 2001 letter, partially redacted, is attached as Exhibit 6.

10. After discussing the invention with Mr. Collins, I revised the application and forwarded the revised application in an e-mail attachment. A copy of the e-mail dated 5/4/01 is attached as Exhibit 7.

11. The application papers were received by Cordis and forwarded to Larry Dominguez for his review on May 9, 2001. A copy of the May 9, 2001 correspondence, partially redacted, is attached as Exhibit 8.

12. The application was reviewed by Mr. Dominguez and the declaration was signed by Mr. Dominguez on May 24, 2001. A copy of the signed declaration is attached as Exhibit 9.

13. On May 31, 2001, a patent draftsman was requested to prepare formal drawings for the patent application. A copy of the May 31, 2001 letter to the patent draftsman is attached as Exhibit 10.

14. On June 11, 2001, the patent application was filed at the PTO.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: March 3, 2004

By:   
George H. Gerstman

**S. C. PELLEGRINO RESEARCH, INC.**

Intellectual Property Searches

10/18/2000

EXHIBIT

10204 Carol Street  
Great Falls, VA 22066

Phone 703-759-9605

Fax 703-759-2055

October 18, 2000

Ms. Grace De La Torre  
Johnson and Johnson  
Cordis Corporation  
14201 N.W. 60th Avenue  
Miami Lakes, FL 33014

RE: Patentability Search for "Microcatheter"  
Invention Disclosure No.: 00/187

Dear Grace,

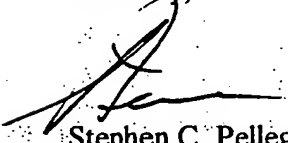
In response to your request received September 21, 2000, a patentability search has been conducted on a catheter as set forth in the invention disclosure. The search focused on a catheter having a balloon that extends from one side of the catheter and a delivery port on the opposite side of the balloon.

Ms. Grace De La Torre  
October 18, 2000  
Page 2

A computer search was also conducted using the Patent Office databases. A number of key words were developed using relevant terms consistent with the subject matter and each patent in the respective set was reviewed.

Should you have any questions regarding this search, please call me at any time.

Sincerely,

A handwritten signature in black ink, appearing to read 'Stephen C. Pellegrino', is written over the typed name.

Stephen C. Pellegrino

SCP/pep  
Enclosure

# Cordis

a Johnson & Johnson company

00/187 88

## DESCRIPTIVE TITLE:

- I. **INSTRUCTIONS:** This form should be typed, except for the signatures and dates. Disclose only one invention on this Invention Disclosure form, and complete the entire form as fully as possible. Forward the completed form to the Legal Department, signed and dated by all inventors and two witnesses. Refer to this Invention Disclosure by the number assigned to it when receipt is acknowledged. Attach additional sheets if more space is required. Each original piece of paper must be signed and dated by every inventor and by each witness.
- II. **ILLUSTRATION:** Include a drawing, sketch, photograph, flow chart, or preferably an engineering quality printout of the invention.

See attached data sheets.

Name & Signature of Inventor(s):

Date

Witnesses

Date

*Walter D. Boring*  
*WDB*

*David H. Boring*  
*David H. Boring*

**III. EXPLANATION OF INVENTION:**

*The micro-catheter consists of a multiple port hub, a multiple lumen body, and a balloon.*

*The multiple port hub is attached to the proximal end of the catheter body. At least one port is in fluid communication with the balloon via the inflation lumen. A secondary port may also be in fluid communication with the balloon. The secondary port and lumen would be used to purge air trapped in the balloon and body. A third port would be used to deliver guide wires, embolics, diagnostic, and therapeutic agents via a delivery lumen.*

*The multiple lumen body is composed of polymers and/or metals and is attached to the multiple port hub at the proximal end and attached to the balloon at the distal end. The balloon is attached to or formed of the distal tip of the dual lumen. The delivery lumen is attached at the proximal end to the delivery port of the hub and exposed at the distal end proximal of the distal tip. This allows for the delivery of embolics, diagnostic, and therapeutic agents via a delivery lumen in a lateral approach as opposed to the traditional distal tip approach.*

*The balloon is composed of polymers. The balloon may be performed and attached to the inflation lumen at the distal tip of the catheter or formed from the inflation lumen of the multiple lumen body.*

**IV. NOVEL FEATURES AND ADVANTAGES:**

*The ability to deliver embolic, diagnostic, and/or therapeutic agents in a lateral approach and position the micro catheter via a balloon.*

**V. MODIFICATIONS:**

*The delivery lumen could be kept intact without a cut. This would allow for the delivery of embolics, diagnostic, and therapeutic agents via the distal tip of the delivery lumen.*

**VI. RELATED DOCUMENTS:** List all known relevant art references (patents, publications, commercially available products, etc.) Please supply copies of the documents, if available.

Patents:

Publications:

Signature of Inventor(s):

*Carlos Dominguez*

Date:

Witnesses:

*Donald K. Jones*

Date:



VII. INVENTORS:

First Inventor's Full name (Please type):

Larry Dominguez

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Second Inventor's Full Name (Please type):

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

VIII. WITNESSES: This invention was disclosed to and understood by:

Full Name of First Witness (Please type):

Boris Shkolnik

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Full Name of Second Witness (Please type):

Don Jones

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

IX. ADDITIONAL INFORMATION:

Invention is recorded on page(s): 81-82 of Notebook No.: 91251 dated: \_\_\_\_\_

Earliest date: \_\_\_\_\_ and place: Cordis Endovascular Systems where inventors first thought of the present invention.

First written description (date and present location): \_\_\_\_\_

First sketch of the invention (date and present location): \_\_\_\_\_ Cordis Endovascular Systems

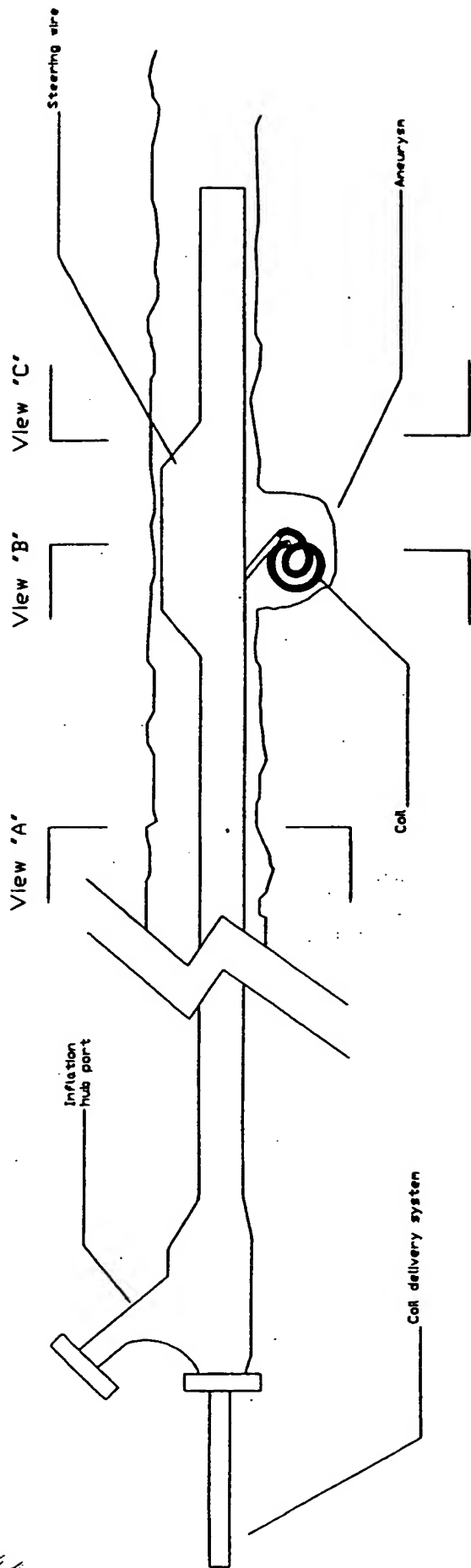
Earliest date: N/A and place: N/A where first operating model was completed.

Present location of model: N/A

Earliest date of use of the invention (actual or contemplated): N/A

Earliest shipping date (actual or contemplated): N/A

# Illustration of catheter treating an aneurysm



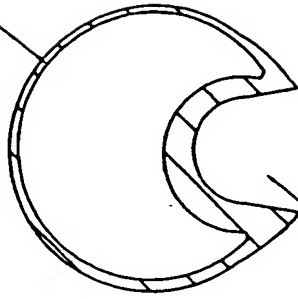
Sanjay Domigues

Sanjay Domigues

Domigues & Son

Balloon  
(inflated)

View 'B'

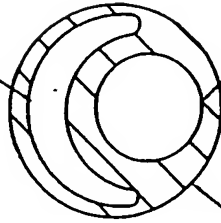


Delivery port

Inflation lumen  
(deflated)

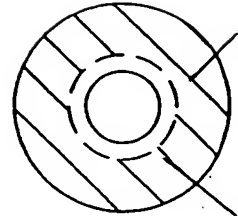
Delivery lumen

View 'A'



Dual lumen  
polymer body

View 'C'



Original I.D.

Reduced I.D.

Emily Dominguez

Donald K. Jones

James H. Smith

**De La Torre, Grace [CRDUS]**

---

**From:** De La Torre, Grace [CRDUS]  
**Sent:** Tuesday, March 27, 2001 4:18 PM  
**To:** 'ggerstman@seyfarth.com'  
**Subject:** Invention Disclosures

Mr. Gerstman,

I am sending you via Federal Express the following invention disclosures, along with copies of the search reports:

00/187 "Microcatheter" - Priority #1

Please acknowledge receipt of this e-mail message.

Grace De La Torre  
Legal Assistant/Patent Liaison  
Phone: 305-824-2042  
Fax: 305-824-2747  
e-mail: gdelator@crdus.jnj.com

**SEYFARTH SHAW  
MEMORANDUM**

**TO:** File  
**FROM:** George H. Gerstman  
**DATE:** March 28, 2001  
**RE:** Cordis IR 00/187

---

#20074971

**SEYFARTH**  
ATTORNEYS **SHAW**

(312) 269-8567

Writer's direct phone

ggerstman@seyfarth.com  
Writer's e-mail

**PATENT**

**APR 10 2001**

**PATENT**

55 East Monroe Street

Suite 4200

Chicago, IL 60603-5803

312-346-8000

fax 312-269-8869

www.seyfarth.com

April 4, 2001

Henry W. Collins, Esq.  
Cordis Corporation  
14201 NW 60th Avenue  
Miami Lakes, Florida 33102-5700

Re: Dominquez U.S. Patent Application for:  
DELIVERY SYSTEM USING BALLOON CATHETER  
Your Ref: IR 00/187; Our Ref. 25647-400187

Dear Hank:

I am enclosing a draft of a patent application concerning the above invention. I would appreciate it if the inventor, Larry Dominquez, would review this and let me know what revisions, if any, are needed. I also need to know his residence address and to which company the application should be assigned.

Best regards.

Cordially yours,

SEYFARTH SHAW

  
George H. Gerstman

GHG/ajw  
Enclosure  
10224584

ATLANTA BOSTON CHICAGO HOUSTON LOS ANGELES NEW YORK SACRAMENTO SAN FRANCISCO WASHINGTON, D.C. BRUSSELS

# Memorandum

**Cordis**

a Johnson & Johnson company

**Date:** April 20, 2001  
**To:** Larry Dominguez  
**From:** Henry W. Collins *Handwritten initials*  
**Subject:** "Delivery System Using Balloon Catheter"  
Invention Record No.: 00/187

Cordis Corporation  
14201 N.W. 60th Avenue  
Miami Lakes, FL 33014  
(305) 824-2000  
(305) 824-2080 Fax

Mailing Address:  
P.O. Box 025700  
Miami, FL 33102-5700

Please review the enclosed draft patent application and make any necessary revisions directly on the application and return it to me at your earliest convenience.

Also, please provide me with your residence address and advise me if you are a U.S. citizen.

HWC/ct

Enclosure

**From:** George Gerstman  
**To:** Hcollins@crdus.jnj.com  
**Date:** 5/4/01 1:27PM  
**Subject:** IR/ 001187

Hank, I have attached the revised application. Please do not hesitate to call me to discuss it.

George H. Gerstman  
SEYFARTH SHAW  
55 East Monroe Street  
Suite 4200  
Chicago, IL 60603

Tel. 312.269.8567  
Fax. 312.269.8869  
e-mail: ggerstman@seyfarth.com



# Memorandum

**Cordis**  
a Johnson & Johnson company

**Date:** May 9, 2001  
**To:** Larry Dominguez  
**From:** Henry W. Collins *Handwritten signature*  
**Subject:** "Delivery System Using Balloon Catheter"  
Our Docket No.: CRD0937

Cordis Corporation  
14201 N.W. 60th Avenue  
Miami Lakes, FL 33014  
(305) 824-2000  
(305) 824-2080 Fax

Mailing Address:  
P.O. Box 025700  
Miami, FL 33102-5700

Please review the enclosed revised patent application and if it meets with your approval, please sign the enclosed Declaration and Assignment form before a Notary Public.

Please return the executed patent application to me at your earliest convenience.

HWC/ct

Enclosure

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

<b>DECLARATION AND POWER OF ATTORNEY FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)</b>	Attorney Docket Number	CRD0937	
	First Named Inventor	Larry Dominguez	
	<b>COMPLETE IF KNOWN</b>		
	Application Number	Unknown	
	Filing Date		
	Group Art Unit	Unknown	
<input checked="" type="checkbox"/> Declaration Submitted with Initial Filing <input type="checkbox"/> Declaration Submitted after Initial Filing (Surcharge (37 CFR 1.16(e)) required)      OR		Examiner Name	Unknown

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.  
 I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

**DELIVERY SYSTEM USING BALLOON CATHETER**  
*(Title of the Invention)*

the specification of which

☒ is attached hereto

OR

☐ was filed on (MM/DD/YYYY)  as United States Application Number or PCT International Application Number  and was amended on (MM/DD/YYYY)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES      NO
			<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

### DECLARATION - Utility or Design Patent Application

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)	
		<input type="checkbox"/> Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No.	Filing Date	Status
		Patented Patented Patented

I hereby appoint:

☒ Practitioners at Customer Number **000027777** →

Place Customer  
Number Bar Code  
Label Here

AND

☐ Practitioner(s) named below:  
Name

Registration Number

as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

Address all telephone calls to Henry W. Collins at telephone number (305) 824-2707.

Direct all correspondence to: Customer Number ☒ or Bar Code Label **000027777** OR ☐ Correspondence address below

Name:

Address:

Address:

City:

State:

ZIP

Country

Telephone:

Fax:

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR:

☐ A petition has been filed for this unsigned inventor

Given Name  
(first and middle [if any]) Larry

Family Name  
Or Surname Dominguez

Inventor's  
Signature

Date 05-24-01

Residence: City West Miami

State Florida

Country U.S.A.

Citizenship U.S.A.

Mailing Address 6121 S.W. 15 Street

City West Miami

State Florida

ZIP 33144

Country U.S.A.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SECOND INVENTOR:

☐ A petition has been filed for this unsigned inventor

Given Name  
(first and middle [if any])

Family Name  
or Surname

Inventor's  
Signature

Date

Residence: City

State

Country

Citizenship

Mailing Address

City

State

ZIP

Country

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF THIRD INVENTOR:

☐ A petition has been filed for this unsigned inventor

Given Name  
(first and middle [if any])

Family Name  
or Surname

Inventor's  
Signature

Date

Residence: City

State

Country

Citizenship

Mailing Address

City

State

ZIP

Country

Johnson & Johnson

OFFICE OF  
GENERAL COUNSEL

14201 N.W. 60TH AVENUE  
MIAMI LAKES, FL 33014

May 31, 2001

Mr. Richard A. Nolan  
939 Ridgeway Avenue  
Munster, Indiana 46321

Re: Patent Application entitled, "Delivery System Using Balloon Catheter"  
Our Docket No. CRD0937

Dear Rick:

Please prepare formal drawings for the above-referenced patent application.

If possible, I would like to have these drawings on June 8.

Very truly yours,



Henry W. Collins  
Attorney

HWC/ct

Enclosure